K060209 MAR 2 2006 p.1/2

TORNIER

Implants Chirurgicaux

Summary of Safety and Effectiveness information
Special 510(k) Premarket Notification – Aequalis Shoulder Fracture System
Aequalis Shoulder System

Regulatory authority: Safe Medical Devices Act of 1990, 21 CRF 807.92

1) Device name

Trade name:	***Aequalis Shoulder Fracture System & Aequalis Shoulder System***
Common name:	Hemi or Total Shoulder Prosthesis
Classification name:	§ 888.3660 Shoulder joint metal/polymer semi-constrained cemented prosthesis

2) Submitter

Tornier S.A.
B.P. 11 - Rue Doyen Gosse
38330 Saint Ismier - France

3) Company contact

Tornier
Mrs Mireille Lémery
Regulatory affairs Manager
161, rue Lavoisier - Montbonnot
38334 Saint Ismier Cedex - France
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4) Classification

Device class:	Class II
Classification panel:	Orthopedic
Product code:	KWS

5) Equivalent / Predicate device

For the AEQUALIS Shoulder Fracture System:
AEQUALIS Shoulder system, TORNIER SA, K952928, K041339, K043077
AEQUALIS Shoulder Fracture system, TORNIER SA, K994392, K003728, K032679, K043077

For the AEQUALIS Shoulder System:
AEQUALIS Shoulder system, TORNIER SA, K952928, K041339, K043077

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FRANCE

Tél. : 33 (0)4 76 61 35 00
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S.A.S. au capital de 288 000 €
SIRET : 070 501 275 000 13
R.C.S. : 070 501 275
CODE APE : 331 B

SIEGE SOCIAL : rue du Doyen Gosse - 38330 SAINT-ISMIER - FRANCE

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6) Device description

The usual goal of total shoulder replacement and hemi-arthroplasty of the shoulder is to restore the shoulder joint to its best working condition and to reduce or eliminate pain. The *Aequalis Shoulder Fracture System* is intended to accomplish these goals. With the *Aequalis Shoulder Fracture System*, the natural glenoid elements of the shoulder may be conserved or replaced as warranted by the state of disease or injury. Thus the *Aequalis Shoulder Fracture System* is intended for use as a total shoulder replacement system, or as a hemi-shoulder. The modular nature of the system allows for the later conversion of a primary hemi-arthrosplasty to a total shoulder replacement.

The present submission corresponds to the following modifications:

- addition of two large glenoid components to the four existing sizes of glenoid both for the *Aequalis shoulder Fracture System* and the *Aequalis shoulder System,*
- addition of a model of Fracture Stem covered with hydroxylapatite to the *Aequalis shoulder Fracture System,* the new stem is strictly identical to the previously cleared device except for the coating.

7) Materials

The humeral implant is manufactured from titanium alloy (Ti6Al4V) in accordance with ISO standard 5832-3 or in chromium-cobalt alloy (CrCo) according to ISO standard 5832-7, ISO standard 5832-12 or ISO standard 5832-4. The glenoid component is made of ultra high molecular weight polyethylene (UHMWPE) according to ISO standard 5834-2.
The hydroxylapatite coating conforms to the ASTM standard F 1185. The coating is performed by BioCoat, Inc. according to their Master File MAF-339.

8) Indications

AEQUALIS Shoulder Range (except AEQUALIS for Fracture):
Prosthetic replacement with this device may be indicated to relieve severe pain or significant disability caused by:

- Degenerative pathologies : arthrosis, rheumatoid arthritis, post-traumatic arthrosis. Primary and secondary necrosis of the humeral head
- Displaced 4-part upper humeral fracture
- Humeral head fracture
- Other pathologies where arthrodesis or resectional arthroplasty of the humeral head are not acceptable
- Revision surgery when other treatments or devices have failed.

AEQUALIS for Fracture:
Traumatic or pathologic conditions of the shoulder resulting in fracture of the glenohumeral joint, including humeral head fracture and displaced 3-or 4-part proximal humeral fractures.
Revision surgery when other treatments or devices have failed.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 2006

Tornier S.A.
C/O Mrs. Mireille Lemery
Regulatory Affairs Manager
161, Rue Lavoisier- Montbonnot
38334 Saint Ismier Cedex
France

Re: K060209
Trade/Device Name: Aequalis Shoulder Fracture System & Aequalis Shoulder System
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KWS
Dated: January 25, 2006
Received: January 31, 2006

Dear Mrs. Lemery:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson, MS
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060209

Device Name: *Aequalis Shoulder Fracture System*
Aequalis Shoulder System

Indications For Use:

AEQUALIS Shoulder Range (except AEQUALIS for Fracture):
Prosthetic replacement with this device may be indicated to relieve severe pain or significant disability caused by:

- Degenerative pathologies : arthrosis, rheumatoid arthritis, post-traumatic arthrosis. Primary and secondary necrosis of the humeral head
- Displaced 4-part upper humeral fracture
- Humeral head fracture
- Other pathologies where arthrodesis or resectional arthroplasty of the humeral head are not acceptable
- Revision surgery when other treatments or devices have failed.

AEQUALIS for Fracture:
Traumatic or pathologic conditions of the shoulder resulting in fracture of the glenohumeral joint, including humeral head fracture and displaced 3-or 4-part proximal humeral fractures.
Revision surgery when other treatments or devices have failed.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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510(k) Number_____